Summary of Safety and Effectiveness Data

I. General Information

Device Generic Name:	Vascular Hemostasis Device
Device Trade Name:	StarClose™ Vascular Closure System
Applicant:	Abbott Vascular Devices 400 Saginaw Drive Redwood City, California 94063
Premarket Approval Application (PMA) Number:	P050007/S001
Date of Panel Recommendation:	None
Date of Notice of Approval to Applicant:	February 2, 2007

On December 21, 2005, the StarClose Vascular Closure System (P050007) was approved for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis, ambulation and dischargeability in patients who have undergone diagnostic endovascular catheterization procedures utilizing a 5 F or 6 F procedural sheath. For more information on the data which supported the original indication, the summary of safety and effectiveness data (SSED) to the original PMA should be referenced. Written requests for copies of the summary of safety and effectiveness data can be obtained from the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, rm. 1-23, Rockville, MD 20857 and may be found on the FDA CDRH Internet Homepage located at http://www.fda.gov/cdrh/pmapage.html.

The sponsor submitted this supplement to expand the indication for use to include the percutaneous closure of common femoral artery access sites while reducing times to hemostasis, and ambulation in patients who have undergone interventional endovascular catheterization procedures utilizing a 5 Fr. or 6 Fr. procedural sheath.

II. Indications for Use

The StarClose™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis and ambulation, in patients who have undergone diagnostic or interventional endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

The StarClose™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing time to dischargeability in patients who have undergone diagnostic endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

III. Contraindications

There are no known contraindications to the use of the StarClose™ Vascular Closure System.

IV. Warnings and Precautions

The Warnings and Precautions can be found in the StarClose™ Vascular Closure System labeling.

V. Device Description

A. Materials and Configuration

The StarClose™ Vascular Closure System is designed to deliver a nitinol clip to close femoral artery access sites following percutaneous catheterization procedures.

The StarClose™ Vascular Closure System consists of the StarClose Clip Applier and a StarClose 6F Exchange System. An implantable Clip is mounted on the Clip Applier, which delivers the Clip through the exchange system or introducer sheath for extravascular closure of access sites. The StarClose™ Vascular Closure System can also be used with the StarClose™ 6F Introducer Set, which is packaged and sold separately.

B. Principles of Operation for the StarClose™ Vascular Closure System:

At the end of the endovascular diagnostic or interventional procedure the user ensures placement of either a StarClose™ Exchange Sheath or StarClose™ Introducer Sheath at the access site. Either sheath is used to introduce and position the StarClose™ Clip Applier.
The distal end of the Clip Applier features a vessel locator. The locator is designed as collapsible nitinol bands that extend into an "X" shape. The expanded locator is gently pulled until it meets with the inner surface of the vessel wall. After aligning the clip applier, the clip is deployed, drawing the edges of the arterial puncture together. The vessel locator simultaneously retracts so that the device may be removed.

VI. Alternative Practices and Procedures

Alternative practices for achieving hemostasis of the femoral artery puncture site post-catheterization include manual compression, mechanical compression, collagen-based hemostasis devices, and percutaneous delivery of sutures to the femoral artery access site. Pressure dressings and sandbags are routinely used in combination with compression methods to control oozing.

VII. Marketing History

The StarClose™ Vascular Closure System has been marketed in the United States for the same intended use for the diagnostic patient population under P050007. Refer to P050007 SSED for foreign marketing information. The StarClose™ Vascular Closure System has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VIII. Potential Adverse Effects of the Device on Health

The use of the StarClose™ Vascular Closure System in diagnostic catheterization patients was evaluated in a pivotal, prospective, multi-center, open-label, randomized clinical study involving 208 diagnostic patients and 275 interventional patients (483 total randomized patients) enrolled at 17 United States clinical centers. The first randomized patient was enrolled on 3/15/04 and enrollment in the interventional arm of the study was completed on 11/11/04. In the interventional arm the StarClose device was compared to standard compression (SC) methods following cardiac and peripheral vascular catheterization procedures utilizing 5F and 6F sheath sizes. The interventional patients were randomized using a 2:1 scheme (StarClose device vs. SC control). Of the 275 interventional patients, 184 patients (66.9%) were randomized to the StarClose device and 91 patients (33.1%) were randomized to SC. A subset of 86 patients in the interventional arm received GP IIb/IIIa inhibitors. Of the 86 interventional patients, 56 patients (65.1%) were randomized to the StarClose device and 30 patients (34.9%) were randomized to SC. All primary analyses comparing the 2 randomized groups were based on an intent-to-treat (ITT) analysis in which patients were assigned to the treatment group to which they were randomized.

The 30-day safety and effectiveness results for the interventional subjects assigned to the StarClose VCS compared favorably to the control group. For all subjects within each treatment group, the major vascular complications rate was 2/184 (1.1%) for the StarClose VCS group and 1/91 (1.1%) for the control group (p=1.000). The total number of major events in the StarClose group was 3 due to 1 subject who had 2 major vascular complications.
The numbers and percentages of major and minor complications for the interventional patients in the clinical study are shown in Table 1 and Table 2.

This interventional arm was further categorized into 86 subjects receiving glycoprotein (GP) IIb/IIIa inhibitors and 189 subjects not receiving GP IIb/IIIa inhibitors during their procedures. For the group of subjects in whom GP IIb/IIIa inhibitors was administered, the major and minor vascular complication rates were 3.6% (3/56) and 8.9% (5/56), respectively, for subjects receiving StarClose, and 0.0% (0/30) and 13.3% (4/30), respectively, for control subjects. The differences between the treatment arms were non-significant with p=0.540 for the major vascular complication rate and p=0.713 for the minor vascular complication rate.

Table 1: Major and Minor Complications Through 30 Days – Interventional ITT Patients

Description of Event	CLIP Device (N=184)	Standard Compression (N=91)	All Patients (N=275)	Difference [95% C.I.]	P-value
Major Vascular Complications (Composite)	1.1% (2/184)	1.1% (1/91)	1.1% (3/275)	-0.0% [-4.9%, 2.9%]	1.000
Vascular Injury Requiring Repair	0.5% (1/184)	0.0% (0/91)	0.4% (1/275)	0.5% [-3.5%, 3.0%]	1.000
Surgery*	0.5% (1/184)	0.0% (0/91)	0.4% (1/275)	0.5% [-3.5%, 3.0%]	1.000
Angioplasty	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Other Percutaneous Procedure	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
New Ipsilateral Lower Extremity Ischemia	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Access Site-related Bleeding Requiring Transfusion*/**/***	1.1% (2/184)	1.1% (1/91)	1.1% (3/275)	-0.0% [-4.9%, 2.9%]	1.000
Antibiotics or Prolonged Hospitalization	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Access Site-related Nerve Injury Requiring Intervention	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Complications					
Death	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Minor Vascular Complications (Composite)	4.3% (8/184)	9.9% (9/91)	6.2% (17/275)	-5.5% [-13.7%, 0.6%]	0.107
Pseudoaneurysm**	0.0% (0/184)	1.1% (1/91)	0.4% (1/275)	-1.1% [-6.0%, 1.1%]	0.331
Arteriovenous Fistula	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Hematoma (>=6 cm)***	4.3% (8/184)	7.7% (7/91)	5.5% (15/275)	-3.3% [-11.0%, 2.3%]	0.268
Late access site-related bleeding	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Transient lower extremity ischemia	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Ipsilateral deep vein thrombosis	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Access site-related nerve injury w/o intervention	0.0% (0/184)	1.1% (1/91)	0.4% (1/275)	-1.1% [-6.0%, 1.1%]	0.331
Access site-related vessel injury	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Access site wound dehiscence	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Ultrasound Compression or Thrombin Injection**/****	0.0% (0/184)	1.1% (1/91)	0.4% (1/275)	-1.1% [-6.0%, 1.1%]	0.331
Re-bleeding at time of first ambulation, req.>30 min. for re-hemostasis	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
Localized access site infection treated with IM or oral antibiotics	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--
UADE	0.0% (0/184)	0.0% (0/91)	0.0% (0/275)	0.0% [-4.1%, 2.0%]	--

Numbers are % (events/sample size).

95% Confidence Interval of difference 0.0% was provided using Newcombe approach.

P-value was provided using Fisher's Exact Test.

*One subject had 2 major vascular events (Surgery and Access site-related bleeding requiring transfusion) and 1 minor vascular event (Hematoma >=6cm).

**One subject had 1 major vascular event (Access site-related bleeding requiring transfusion) and 3 minor vascular events (Pseudoaneurysm and 2 occurrences of Ultrasound Compression or Thrombin injection).

***One subject had 1 major vascular event (Access site-related bleeding requiring transfusion) and 1 minor vascular event (Hematoma >=6cm)

****The protocol states ultrasound compression and thrombin injection were classified as major vascular complications, however, these have since been reclassified as minor vascular complications per the FDA.

Table 2: Major and Minor Complications Through 30 Days – Interventional ITT Patients Receiving Glycoprotein IIb/IIIa Inhibitors

Description of Event	StarClose (N=56)	Standard Compression (N=30)	All Subjects (N=86)	Difference [95% C.I.]	P-value
Major Vascular Complications (Composite)	3.6% (2/56)	0.0% (0/30)	2.3% (2/86)	3.6% [-8.1%,12.1%]	0.540
Vascular Injury Requiring Repair	1.8% (1/56)	0.0% (0/30)	1.2% (1/86)	1.8% [-9.7%,9.4%]	1.000
Surgery*	1.8% (1/56)	0.0% (0/30)	1.2% (1/86)	1.8% [-9.7%,9.4%]	1.000
Angioplasty	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Other Percutaneous Procedure	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
New Ipsilateral Lower Extremity Ischemia	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Access Site-related Bleeding Requiring Transfusion*/**	3.6% (2/56)	0.0% (0/30)	2.3% (2/86)	3.6% [-8.1%,12.1%]	0.540
Antibiotics or Prolonged Hospitalization	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Access Site-related Nerve Injury Requiring Intervention	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Complications					
Death	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Minor Vascular Complications (Composite)	8.9% (5/56)	13.3% (4/30)	10.5% (9/86)	-4.4% [-18.7%,9.9%]	0.713
Pseudoaneurysm	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Arteriovenous Fistula	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Hematoma (>=6 cm)*/**	8.9% (5/56)	13.3% (4/30)	10.5% (9/86)	-4.4% [-18.7%,9.9%]	0.713
Late access site-related bleeding	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Transient lower extremity ischemia	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Ipsilateral deep vein thrombosis	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Access site-related nerve injury w/o intervention	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Access site-related vessel injury	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Access site wound dehiscence	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Ultrasound Compression or Thrombin Injection***	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Re-bleeding at time of first ambulation req.>30 min. for re-hemostasis	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
Localized access site infection treated with IM or oral antibiotics	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--
UADE	0.0% (0/56)	0.0% (0/30)	0.0% (0/86)	0.0% [-11.4%,6.4%]	--

Numbers are % (events/sample size).

95% Confidence Interval of difference 0.0% was provided using Newcombe approach.

P-value was provided using Fisher's Exact Test.

*One StarClose subject 16-301 had 2 major vascular events (Surgery and Access site-related bleeding requiring transfusion) and 1 minor vascular event (Hematoma >=6cm).

**One StarClose subject 03-313 had 1 major vascular event (Access site-related bleeding requiring transfusion) and 1 minor vascular event (Hematoma >=6cm)/

***The protocol states ultrasound compression and thrombin injection were classified as major vascular complications, however, these have since been reclassified as minor vascular complications per the FDA.

IX. Summary of Preclinical Studies

Please refer to the preclinical data in the SSED for the original PMA (P050007). No additional preclinical studies were required for this supplement.

X. Clinical Studies

A. StarClose™ Vascular Closure System U.S. IDE Multi-Center, Randomized Clinical Trial

The use of the StarClose Vascular Closure System in diagnostic and interventional catheterization patients was evaluated in a pivotal, prospective, multi-center, open-label, randomized clinical study involving 208 diagnostic patients and 275 interventional patients (483 total randomized patients) enrolled at 17 United States clinical centers. The first randomized patient was enrolled on 3/15/04.

Enrollment in the interventional arm of the study was completed on 11/11/04. In the interventional arm the StarClose device was compared to standard compression (SC) methods following cardiac and peripheral vascular catheterization procedures utilizing 5F and 6F sheath sizes. The interventional patients were randomized using a 2:1 scheme (StarClose device vs. SC control). Of the 275 interventional patients, 184 patients (66.9%) were randomized to the StarClose device and 91 patients (33.1%) were randomized to SC. A subset of 86 patients in the interventional arm received GP IIb/IIIa inhibitors. Of the 86 interventional patients, 56 patients (65.1%) were randomized to the StarClose device and 30 patients (34.9%) were randomized to SC. All primary analyses comparing the 2 randomized groups were based on an intent-to-treat (ITT) analysis in which patients were assigned to the treatment group to which they were randomized.

The randomized interventional patients in the study had to meet general inclusion criteria, general exclusion criteria, access site exclusion criteria (including some criteria evaluated via limited femoral artery angiogram), and procedural exclusion criteria. The interventional patients consisted of 80.4% men and ranged in age from 39 to 81. The interventional patients who were randomized to the StarClose device were asked to ambulate 4 hours after the interventional procedure was complete, and the interventional patients who were randomized to SC were ambulated according to institutional standards and guidelines.

The primary safety endpoint for the study was the combined rate of major complications within 30 ± 7 days following the catheterization procedure. The secondary safety endpoint for the study was the combined rate of minor complications within 30 ± 7 days following the catheterization procedure. The null hypothesis for safety was that the StarClose Vascular Closure System had a primary safety endpoint rate exceeding that of the standard of care (standard

compression) by delta. The alternative hypothesis was that the StarClose Vascular Closure System had a primary safety endpoint rate less than that of standard compression or exceeding that of standard compression by no more than delta; i.e.,

H_o: $\pi_{IC} > \pi_{SC} + \delta$
H_a: $\pi_{IC} \leq \pi_{SC} + \delta$

where π_{IC} was the primary endpoint rate estimated for the StarClose Vascular Closure System and π_{SC} was the primary endpoint rate estimated for the standard of care (standard compression).

For the interventional patients, the StarClose device also demonstrated safety. By Day 30, a combined total of 2 (1.1%) major complications was reported for the randomized interventional patients who received the StarClose device, and a combined total of 1 (1.1%) major complications was reported for the randomized interventional patients who received SC.

For the interventional patients, the rates of minor complications were low between the 2 randomized treatment groups. Of the 17 minor vascular complications noted, 8 occurred in the StarClose device group and 9 minor complications occurred in the control. The combined total rates of minor complications at Day 30 were 4.3% for the randomized diagnostic StarClose device patients and 9.9% for the randomized diagnostic SC patients.

The primary effectiveness endpoint for the interventional study was time to hemostasis. The secondary effectiveness endpoints were time to ambulation, procedure success at discharge, and device success.
Time to hemostasis was defined as the elapsed time between sheath removal and first observed hemostasis. Time to ambulation was defined as the elapsed time between sheath removal and the time when the patient stands and walks at least 20 feet without re-bleeding.

Procedure success was defined as the attainment of final hemostasis using any method and freedom from major vascular complications.
Device success was defined as the attainment of final hemostasis using the StarClose Vascular Closure System alone or with adjunctive compression ≤ 5 minutes and freedom from major vascular complications.

The effectiveness results for the interventional patients in the clinical study are shown in Table 6, Table 7, and Table 8.

Table 6: Primary Effectiveness Endpoint – Interventional ITT Patients

Time to Hemostasis (Mins)	CLIP Device (N=184)	Standard Compression (N=91)	All Patients (N=275)	Difference [95% C.I.]	P-value***
Mean ± SD (N)	7.95 ± 28.22 (182)	29.06 ± 35.26 (74)	14.05 ± 31.83 (256)	-14.01 [-16.21, -11.81]	<0.001
Median	0.33	19.60	1.83		
Range (min, max)	(0.0, 184.2)	(0.0, 245.3)	(0.0, 245.3)		

Numbers are % (counts/sample size) or Mean ± 1 Standard Deviation.

Treatment group comparisons were performed using Fisher's Exact test for categorical variables. For continuous variables, the Shapiro-Wilk test was used to test normality of Time to Hemostasis and Time to Ambulation. The p-value from this test was <0.001, indicating non-normality and skewness of the data distribution. Therefore the Wilcoxon Rank Sum Test was used to calculate the p-value between the two groups.

Table 7: Secondary Effectiveness Endpoints – Interventional ITT Patients

Interventional	StarClose Device (N=184)	Standard Compression (N=91)	All Subjects (N=275)	Difference [95% C.I.]	P-value
Procedure Success*	98.9% (181/183)	98.7% (74/75)	98.8% (255/258)	0.2% [-2.8%, 3.2%]	1.000
Device Success**	86.8% (158/182)	N/A	N/A	N/A	N/A
Time to Hemostasis (Mins)***					
Mean±SD (N)	7.95±28.22 (182)	29.06±35.26 (74)	14.05±31.83 (256)	-21.11 [-29.37, -12.85]	<0.001
Range (min, max)	(0.0,184.2)	(0.0,245.3)	(0.0,245.3)		
Median	0.33	19.60	1.83		
Percentile (5%, 95%)	(0.03,27.92)	(13.47,79.67)	(0.03,66.42)		
Time to Ambulation (Mins)****					
Mean±SD (N)	406.99±282.61 (178)	466.02±257.23 (90)	426.82±275.29 (268)	-59.03 [-128.90,10.85]	<0.001
Range (min, max)	(129.0,1686.0)	(41.0,1310.0)	(41.0,1686.0)		
Median	278.50	389.00	305.00		
Percentile (5%, 95%)	(228.00,1075.00)	(235.00,1023.00)	(234.00,1050.00)		

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Numbers are % (counts/sample size) or Mean ± 1 Standard Deviation.

Treatment group comparisons were performed using Fisher's Exact test for categorical variables. For continuous variables, the Shapiro-Wilk test was used to test normality of Time to Hemostasis and Time to Ambulation. The p-value from this test was <0.001, indicating non-normality and skewness of the data distribution. Therefore the Wilcoxon Rank Sum Test was used to calculate the p-value between the two groups.

* Procedure success was defined as the attainment of final hemostasis using any method and freedom from major vascular complications. StarClose subject 01-315 had time of hemostasis (T6) missing; therefore, Procedure Success was incalculable. Standard compression subjects 01-304, 01-307, 01-311, 01-313, 01-317, 01-321, 01-327, 01-332, 01-333, 01-340, 01-355, 03-305, 04-308, 06-317, 06-330, and 16-310 had the "seconds" field incomplete for time of hemostasis (T6), and therefore procedure success was not calculable.

** Device success was defined as the attainment of final hemostasis using the StarClose VCS alone or with adjunctive compression ≤5 minutes and freedom from major vascular complications. Device success could not be calculated for two (2) Starclose subjects; 01-315 had time of hemostasis (T6) missing and 15-307 had time procedural sheath removed (T2) missing.

*** Time to hemostasis was defined as the elapsed time between sheath removal and first observed hemostasis. The time to hemostasis was calculated by subtracting CRF IVC 007, Q. 11.7 (time Introducer sheath removed) from IVC 007, Q.11.8 (time hemostasis first observed) for device subjects, or calculated by subtracting CRF IVC 008, Q. 12.1 (time procedural sheath removed) from IVC 008, Q.12.2 (time hemostasis first observed) for control subjects. StarClose subjects 02-117, 04-303, 04-305, 04-307, 10-305 and control subject 02-304 had time to hemostasis equal to '0'. These values have been queried and confirmed by the investigators. StarClose subjects with incalculable values for TTH were 15-307 and 01-315. Standard compression subjects with incalculable TTH values were: 01-304, 01-307, 01-311, 01-313, 01-317, 01-321, 01-327, 01-332, 01-333, 01-340, 01-355, 03-305, 04-308, 06-317, 06-320, 06-330, and 16-310.

**** Time to ambulation was defined as the elapsed time between sheath removal and time when the subject stood and walked at least 20 feet without re-bleeding. The time to ambulation was calculated by subtracting IVC 007 Q.11.7 (time Introducer sheath removed) for device subjects or IVC 008 Q. 12.1 (time procedural sheath removed) for control subjects, from CRF IVC 011, Q.1.8 (time of first ambulation). StarClose subjects with incalculable time to ambulation values were: 01-315, 02-319, 02-335, 04-304, 06-308, and 15-307. The standard compression subject with an incalculable value for time to ambulation was 01-317.

Table 8: Effectiveness Results by Post-Procedure Time Interval for Interventional ITT Patients

Table 8: Effectiveness Results by Post Procedure Time Interval for Interventional ITT Patients

Percentage of Patients Achieving Hemostasis within Time Interval		< 5 min	< 10 min	< 15 min	< 30 min	< 60 min	≤ 120 min	> 120 min		
	Star Close *	83.2 % (153/ 184)	89.1% (164/ 184)	90.8 % (167/ 184)	94.0% (173/ 184)	94.6% (174/ 184)	96.2% (177/ 184)			
	Stand-ard Compression **	2.7% (2/74)	4.1% (3/74)	10.8% (8/74)	77.0% (57/74)	90.5% (67/74)	97.3% (72/74)			
Percentage of Patients Ambulating Within Time Interval		< 1 hr	< 2 hrs	< 3 hrs	< 4 hrs	< 6 hrs	< 12 hrs	< 18 hrs	≤ 20 hrs	> 20 hrs
	Star Close #	0% (0/184)	0% (0/184)	2.2% (4/184)	5.4% (10/184)	66.3% (122/184)	84.8% (156/184)	92.4% (170/184)	92.9% (171/184)	96.7% (178/184)
	Stand-ard Compression ##	2.2% (2/91)	2.2% (2/91)	2.2% (2/91)	5.5% (5/91)	38.5% (35/91)	83.5% (76/91)	96.7% (88/91)	97.8% (89/91)	98.9% (90/91)

*Table 1 on page 12 of the submission notes there is no data for subjects 01-315 and 15-307, resulting in only 182 StarClose subjects with actual times recorded.
** Note 3 of Table 21 on page 59 of the submission states that 17 subjects had no time to hemostasis recorded, leaving 74 Compression subjects (blue) with actual times recorded. Values in orange include all subjects.
# Six (6) subjects had no time to ambulation noted due to the absence of one or more data points needed to calculate TTA.
One (1) subject had no time to ambulation noted due to the absence of one or more data points needed to calculate TTA.

B. Repuncture Through StarClose and Reclosure

Please refer to the clinical section of the original SSED for repuncture information.

XI. Conclusions Drawn from Studies

Results of the biocompatibility testing, *in vitro* bench testing, animal studies, cadaver study and clinical investigations provide valid scientific evidence and reasonable assurance that the StarClose™ Vascular Closure System is safe and effective when used in accordance with its Instructions for Use.

XII. Panel Recommendation

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by the panel.

XIII. CDRH Decision

FDA issued a PMA approval order to Abbott Vascular Devices on February 2, 2007.

XIV. Approval Specifications

A. Instructions for Use: See the labeling.
B. Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events sections of the labeling.
C. Post Approval Requirements and Restrictions: See approval order.